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(Kathryn Hugo)

Docket No.: GFI/102
(PATENT)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

IN the Patent Application of:
Wildt et al.

Application No.: 10/500,240

Confirmation No.: 3290

Filed: March 23, 2005

Art Unit: 1632

For: METHOD TO ENGINEER MAMMALIAN-
TYPE CARBOHYDRATE STRUCTURES

Examiner: Not Yet Assigned

INFORMATION DISCLOSURE STATEMENT (IDS)

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Commissioner for Patents
P.O. Box 1450
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Dear Sir:

Pursuant to 37 C.F.R. §§§ 1.56, 1.97 and 1.98, the attention of the Patent and Trademark Office is hereby directed to the references listed on the attached PTO/SB/08. It is respectfully requested that the information be expressly considered during the prosecution of this application, and that the references be made of record therein and appear among the "References Cited" on any patent to issue therefrom.

This Information Disclosure Statement is filed before the mailing date of a first Office Action on the merits as far as is known to the undersigned (37 CFR 1.97(b)(3)).

Applicant has not submitted copies of each cited U.S. patent and U.S. patent application as required by 37 CFR 1.98(a)(2)(i), amended October 2004, as the U.S. Patent and Trademark Office has waived this requirement for all U.S. patent applications. Applicant submits herewith copies of foreign and non-patents in accordance with 37 C.F.R. § 1.98(a)(2).

In accordance with 37 C.F.R. § 1.97(g), the filing of this Information Disclosure Statement shall not be construed to mean that a search has been made or that no other material information as defined in 37 C.F.R. § 1.56(a) exists. In accordance with 37 C.F.R. § 1.97(h), the

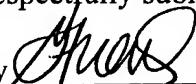
filings of this Information Disclosure statement shall not be construed to be an admission that any patent, publication or other information referred to therein is "prior art" for this invention unless specifically designated as such.

It is submitted that the Information Disclosure Statement is in compliance with 37 C.F.R. § 1.98 and the Examiner is respectfully requested to consider the listed references.

The Director is hereby authorized to charge any deficiency in the fees filed, asserted to be filed or which should have been filed herewith (or with any paper hereafter filed in this application by this firm) to our Deposit Account No. 06-1075, under Order No. GFI/102. A duplicate copy of this paper is enclosed.

Dated: November 4, 2005

Respectfully submitted,

By 
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U.S. PATENT DOCUMENTS					
Examiner Initials*	Cite No. ¹	Document Number	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number-Kind Code ² (if known)			
AA	US 5,595,900	01-21-1997	John B. Lowe		
AB	US 6,300,113	10-09-2001	David Landry		

FOREIGN PATENT DOCUMENTS					
Examiner Initials*	Cite No. ¹	Foreign Patent Document	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
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BA	WO 02/00879		01-03-2002	Gerngross	

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NON PATENT LITERATURE DOCUMENTS					
Examiner Initials	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.			
	CA	Abdel-Salam et al., "Expression of mouse anticontinuous kinase (MAK33) monoclonal antibody in the yeast <i>Hansenula polymorpha</i> ", <i>Appl. Microbiol. Biotechnol.</i> , 56:157-164 (2001).			
	CB	Aebi et al., "Cloning and Characterization of the ALG3 Gene of <i>Saccharomyces cerevisiae</i> " <i>Glycobiology</i> 6(4): 439-444 (1999).			
	CC	Abeijon et al., "Molecular Cloning of the Golgi apparatus uridine diphosphate-N-acetylglucosamine transporter from <i>Kluyveromyces lactis</i> " <i>Proc. Natl. Acad. Sci. USA</i> 93:5963-5968 (1996).			
	CD	Alvarez et al., "Sequences of the mouse N-acetylglucosaminyltransferase V (Mgat5) mRNA and an mRNA expressed by an Mgat-deficient cell line" <i>Glycobiology</i> 12 (7), 389-394 (2002)			
	CE	Aoki et al., "Expression and activity of chimeric molecules between human UDP-galactose transporter and CMP-sialic acid transporter", <i>J. Biochem. (Tokyo)</i> , 126(5):940-50 (1999).			
	CF	Beaudet et al., "High-level expression of mouse Mdr3 P-glycoprotein in yeast <i>Pichia pastoris</i> and characterization of ATPase activity", <i>Methods Enzymol.</i> , 292:397-413 (1998).			
	CG	Berka et al., "The Filamentous Fungus <i>Aspergillus niger</i> var. <i>Awamori</i> as Host for the Expression and Secretion of Fungal and Non-Fungal Heterologous Proteins", <i>Abstr. Papers Amer. Chem. Soc.</i> 203:121-BIOT (1992).			
	CH	Berninsone et al., "The Golgi guanosine diphosphatase is required for transport of GDP-mannose into the lumen of <i>Saccharomyces cerevisiae</i> Golgi vesicles", <i>J. Biol. Chem.</i> , 269(1):207-211 (1994).			
	CI	Berninsone et al., "Regulation of Yeast Golgi Glycosylation", <i>J. Biol. Chem.</i> , 270 (24): 14564-14567 (1995).			

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CJ	Berninson et al., "Functional Expression of the Murine Golgi CMP-Sialic Acid Transporter in <i>Saccharomyces cerevisiae</i> ", <i>J. Biol. Chem.</i> 272(19):12616-9 (1997).
CK	Berninson, "Nucleotide Sugar Transporters of the Golgi Apparatus." <i>Current opinion in Structural Biology, Biology</i> 10: 542-547 (2000)
CL	Bianchi et al., "Transformation of the yeast <i>Kluyveromyces lactis</i> by new vectors derived from the 1.6 μ m circular plasmid pKD1", <i>Current Genetics</i> , 12:185-192 (1987).
CM	Boehm et al., "Disruption of the KEX1 Gene in <i>Pichia pastoris</i> Allows Expression of Full-Length Murine and Human Endostatin", <i>Yeast</i> , 15:563-572 (1999).
CN	Brethauer et al., "Glycosylation of <i>Pichia pastoris</i> -derived proteins", <i>Biotechnology and Applied Biochemistry</i> 30:193-200 (1999)
CO	Burda et al., "A Novel Carbohydrate-Deficient Glycoprotein Syndrome Characterized by a Deficiency in Glucosylation of the Dolichol-Linked Oligosaccharide", <i>J. Clin. Invest.</i> , Vol. 102, No. 4, 647-652, August 1998.
CP	Burda et al., "Stepwise Assembly of the Lipid-Linked Oligosaccharide in the Endoplasmic Reticulum of <i>Saccharomyces Cerevisiae</i> : Identification of the ALG9 Gene Encoding a Putative Mannosyl Transferase", <i>Proc. Natl. Acad. Sci. U.S.A.</i> , July 1996 (93): 7160-7165.
CQ	Cereghino et al., "Heterologous protein expression in the methylotrophic yeast <i>Pichia pastoris</i> ", <i>FEMS Microbiology Reviews</i> , 24(1):45-66 (2000).
CR	Cereghino et al., "New selectable marker/auxotrophic host strain combinations for molecular genetic manipulation of <i>Pichia pastoris</i> ", <i>Gene</i> , 263:159-169 (2001).
CS	Chantret et al., "Congenital Disorders of Glycosylation Type Ig is Defined by a Deficiency in Dolichyl-P-mannose: Man7GlcNAc2-PP-dolichyl mannosyltransferase", <i>J. Biol. Chem.</i> , Jul. 12, 2002 (277) 28:25815-25822.
CT	Chiba et al., "Production of Human Compatible High Mannose-type Sugar Chains in <i>Saccharomyces cerevisiae</i> ", <i>J. Biol. Chem.</i> , 273(41):26298-26304 (1998)
CU	Choi et al., "Use of combinatorial genetic libraries to humanize N-linked glycosylation in the yeast <i>Pichia pastoris</i> ", <i>Proc. Natl. Acad. Sci. USA</i> 100:5022-5027 (2003).
CV	Cipollo et al., "The <i>Saccharomyces Cerevisiae</i> Δ alg12delta Mutant Reveals a Role for the Middle-arm Alpha1,2Man-and Upper-Arm alpha1,2Manalpha1,6Man- Residues of Glc3Man9GlcNAc2-PP-Dol in Regulating Glycoprotein Glycan Processing in the Endoplasmic Reticulum and Golgi Apparatus", <i>Glycobiology</i> 2002, (12) 11:749-762
CW	Cipollo et al., "The Accumulation of Man(6)GlcNAc(2)-PP-dolichol in the <i>Saccharomyces Cerevisiae</i> Δ alg9 Mutant Reveals a Regulatory Role for the Alg3P alpha1,3-Man Middle-Arm Addition in Downstream Oligosaccharide-Lipid and Glycoprotein Glycan Processing", <i>J. Biol. Chem.</i> , Feb. 11, 2000 (275) 6:4267-4277.
CX	Cueva et al., "Preferential Transfer to Truncated Oligosaccharides to the First Sequon of Yeast Exoglycanase in <i>Saccharomyces Cerevisiae</i> alg3 Cells", <i>Biochim. Biophys. Acta</i> , 1289 (3):336-42 (1996).
CY	Davidson et al., "A PCR-based strategy to generate integrative targeting alleles with large regions of homology", <i>Microbiol.</i> , 148(Pt 8):2607-15 (2002).
CZ	Davies et al., "Expression of GnTIII in a Recombinant Anti-CD20 CHO Production Cell Line: Expression of Antibodies with Altered Glycoforms Leads to an Increase in ADCC Through Higher Affinity for Fc γ RIII", <i>Biotechnol. Bioeng.</i> , 74(4):288-294 (2001).
CA1	Duman et al., "O-Mannosylation of <i>Pichia Pastoris</i> Cellular and Recombinant Proteins", <i>Biotechnology and Applied Biochemistry</i> , 1998, Volume 28, pages 39-45.
CB1	Eckhardt et al., "Molecular Cloning of the Hamster CMP-Sialic Acid Transporter", <i>Eur. J. Biochem.</i> , 248(1):187-192 (1997).

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Sheet	3	of	6	Attorney Docket Number	GFI/102

CC1	Fukuta et al., "Comparative Study for the N-Glycans of Human Monoclonal Immunoglobulins M Produced by Hybridoma and Parental Cells", <i>Archives of Biochemistry and Biophysics</i> , 378(1), 142-150 (2000).
CD1	Gibbs et al., "Dolicholpyrophosphate Oligosaccharides: Large-Scale Isolation and Evaluation as Oligosaccharyltransferase Substrates" <i>Bioorganic & Medical Chemistry</i> 7 (1999) 441-447.
CE1	Gleeson, Paul A. "Targeting of Proteins to the Golgi Apparatus", <i>Histochem. Cell Biol.</i> , 109:517-532 (1998).
CF1	Graham et al., "Compartmental Organization of Golgi-specific Protein Modification and Vacuolar Protein Sorting Events Defined in Yeast sec18 (NSF) Mutant", <i>J. Cell. Biol.</i> , 114(2):207-218 (1991).
CG1	Grimme et al., "The essential Smp3 Protein is Required for Addition of the Side-Branching Fourth Mannose During Assembly of Yeast Glycosylphosphatidylinositol", <i>J. Biol. Chem.</i> , July 20, 2001, (276)29:2773-27739.
CH1	Guillen et al., "Mammalian Golgi Apparatus UDP-N-acetylglucosamine Transporter: Molecular Cloning by Phenotypic Correction of a Yeast Mutant", <i>Proc. Natl. Acad. Sci. USA</i> , 95(14):7888-7892 (1998).
CI1	Hamilton et al., "Yeast mutants deficient in protein glycosylation", Production of Complex Human Glycoproteins in Yeast", <i>Science</i> , 301:1244-46 (2003).
CJ1	Hernandez et al., "Structure of the Phosphorylated N-Linked Oligosaccharides from the <i>mnn9</i> and <i>mnn10</i> Mutants of <i>Saccharomyces cerevisiae</i> ", <i>The Journal of Biological Chemistry</i> , 264(23):13648-13659 (1989).
CK1	Huffaker et al., "Yeast Mutants Deficient in Protein Glycosylation", <i>Proc. Natl. Acad. Sci. U.S.A.</i> , Dec. 1983 (80): 7466-7470.
CL1	Imbach, et al. "A Mutation in the Human Ortholog of the <i>Saccharomyces cerevisiae</i> ALG6 Gene Causes Carbohydrate-Deficient Glycoprotein Syndrome Type-Ic.", <i>Proc. Natl. Acad. Sci. U.S.A.</i> , June 1999 (96), 6981-6987.
CM1	Ishida et al., "Molecular Cloning and Characterization of a Novel Isoform of the Human UDP-Galactose Transporter, and of Related Complementary DNAs Belonging to the Nucleotide-Sugar Transporter Gene Family", <i>J. Biochem.</i> , (Tokyo) 120(6):1074-1078 (1996).
CN1	Ishida et al., "Molecular Cloning and Functional Expression of the Human Golgi UDP-N-Acetylglucosamine Transporter", <i>J. Biochem.</i> , 126(1):68-77 (1999).
CO1	Jarvis et al., "Engineering N-glycosylation pathways in the baculovirus-insect cell system", <i>Current Opinion in Biotechnology</i> , 9:528-533 (1998).
CP1	Kainuma, "Coexpression of α 1,2 galactosyltransferase and UDP-galactose transporter efficiently galatosylates N- and O-glycan in <i>Saccharomyces cerevisiae</i> ", <i>Glycobiology</i> , 9(2): 133-141 (1999).
CQ1	Kalsner et al., "Insertion into <i>Aspergillus nidulans</i> of functional UDP-GlcNAc: α 3-D-mannoside β -1,2-N-acetylglucosaminyl-transferase I, the enzyme catalysing the first committed step from oligomannose to hybrid and complex N-glycans", <i>Glycoconj. J.</i> , 12(3):360-370 (1995).
CR1	Karaoglu et al., "Allosteric Regulation Provides a Molecular Mechanism for Preferential Utilization of the Fully Assembled Dolichol-Linked Oligosaccharide by the Yeast Oligosaccharyltransferase", <i>Biochemistry</i> , 2001, 40, 12193-12206.
CS1	Kato et al., "Nucleotide Sequence of a Regulatory Region Controlling Alginate Synthesis in <i>Pseudomonas aeruginosa</i> : Characterization of the <i>AlgR2</i> Gene", <i>Gene</i> , 1989, Volume 84, pages 31-38.
CT1	Krezdorn et al., "Human β 1,4 galactosyltransferase and α 2,6 sialyltransferase expressed in <i>Saccharomyces cerevisiae</i> are retained as active enzymes in the endoplasmic reticulum", <i>Eur. J. Biochem.</i> , 220(3):809-17 (1994).

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CU1	Malissard et al., "Expression of Functional Soluble Forms of Human β -1,4-Galactosyltransferase I, α -2,6-Sialyltransferase, and α -1,3-Fucosyltransferase VI in the Methylotrophic Yeast <i>Pichia pastoris</i> ", <i>Biochemical and Biophysical Research Communications</i> , 267:169-173 (2000).	
CV1	Maras et al., "In vitro conversion of the carbohydrate moiety of fungal glycoproteins to mammalian-type oligosaccharides", <i>Eur. J. Biochem.</i> , 249:701-707 (1997)	
CW1	Maras et al., "In Vivo Synthesis of Complex N-glycans by Expression of Human N-acetylglucosaminyltransferase I in the Filamentous Fungus <i>Trichoderma Reesei</i> ", <i>Febs Letters</i> , 452(3): 365-370 (1999).	
CX1	Martinet et al., "Modification of the Protein Glycosylation Pathway in the Methylotrophic Yeast <i>Pichia pastoris</i> " <i>Biotechnology Letters</i> , 20:1171-1177 (1998)	
CY1	Miele et al., "Glycosylation properties of the <i>Pichia pastoris</i> -expressed recombinant kringle 2 domain of tissue-type plasminogen activator", <i>Biotechnol. Appl. Biochem.</i> , 25:151-157 (1997)	
CZ1	Miele et al., "Glycosylation of Asparagine-28 of Recombinant Staphylokinase with High-Mannose-Type Oligosaccharides Results in a Protein with Highly Attenuated Plasminogen Activator Activity", <i>Journal of Biological Chemistry</i> , 19 March 1999, Volume 274, No. 12, pages 7769-7776.	
CA2	Minowa et al., "cDNA Cloning and Expression of Bovine UDP-N-Acetylglucosamine: α 1, 3-D-Mannoside β 1,4-N-acetylglucosaminyltransferase IV", <i>J. Biol. Chem.</i> , 273 (19), 1998, 11556-11562	
CB2	Moller et al., "Control of Glycoprotein Synthesis: Substrate Specificity of Rat Liver UDP-GlcNAc:Man alpha 3R beta 2-N-Acetylglucosaminyltransferase I Using Synthetic Substrate Analogues", <i>Glycoconj J.</i> , 1992 Aug.; 9(4): 180-90.	
CC2	Nakanishi-Shindo et al., "Structure of the N-Linked Oligosaccharides That Show the Complete Loss of α -1,6-Polymannose Outer Chain from <i>och1</i> , <i>och1 mnn1</i> , and <i>och1 mnn1 alg3</i> Mutants in <i>Saccharomyces cerevisiae</i> " <i>J. Biol. Chem.</i> , 268(35):26338-45 (1993).	
CD2	Omtvedt et al., "Glycosylation of Immunoglobulin Light Chains Associated with Amyloidosis", <i>Amyloid: International Journal of Experimental and Clinical Investigation</i> , 2000, Volume 7, Pages 227-244.	
CE2	Papac et al., "A high-throughput microscale method to release N-linked oligosaccharides from glycoproteins for matrix-assisted laser desorption/ionization time-of-flight mass spectrometric analysis", A.J.S., <i>Glycobiology</i> , 8:445-454 (1998).	
CF2	Perez et al., "Transport of Sugar Nucleotides into the Lumen of Vesicles Derived from Rat Liver Rough Endoplasmic Reticulum and Golgi Apparatus", <i>Methods in Enzymology</i> , 138:709-715 (1987).	
CG2	Puglielli et al., "Reconstitution, Identification, and Purification of the Rat Liver Golgi Membrane GDP-fucose Transporter", <i>J. Biol. Chem.</i> 274(50):35596-35600 (1999).	
CH2	Raju et al., "Species-specific variation in glycosylation of IgG: evidence for the species-specific sialylation and branch-specific galactosylation and importance for engineering recombinant glycoprotein therapeutics", <i>Glycobiology</i> , 10(5):477-486 (2000)	
CI2	Reiss et al., "Isolation of the ALG6 Locus of <i>Saccharomyces Cerevisiae</i> Required for blycosylation in the N-lined Glycosylation Pathway", <i>Glycobiology</i> , 1996, July 6(5):493-8.	
CJ2	Runge et al., "A New Yeast Mutant in the Glucosylation Steps for the Asparagine-Linked Glycosylation Pathway", <i>Journal of Biological Chemistry</i> , 25 November 1986, Volume 261, No. 33, Pages 15582-15590.	
CK2	Schachter et al., "The 'Yellow Brick Road' to Branched Complex N-glycans", <i>Glycobiology</i> 1(5): 453-461, 1991.	

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CL2	Schwientek et al., "Golgi Localization in Yeast is Mediated by the Membrane Anchor Region in Rat Liver Sialyltransferase", <i>J. Biol. Chem.</i> , 270(10):5483-5489 (1995).
CM2	Segawa et al., "Schizosaccharomyces pombe UDP-galactose transporter: identification of its functional form through cDNA cloning and expression in mammalian cells", <i>FEBS Letters</i> , 451(3):295-298 (1999).
CN2	Sharma et al., "Biosynthesis of Lipid-Linked Oligosaccharides in Yeast: The ALG3 Gene Encodes the Dol-P-Man: Man(5)GlcNAc(2)-PP-Dol Mannosyltransferase", <i>Biological Chemistry</i> , 382(2): 321-328 (2001).
CO2	Sommers et al., "Transport of Sugar Nucleotides into Rat Liver Golgi", <i>J. Cell Biol.</i> , 91(2):A406 (1981).
CP2	Sommers et al., "Transport of Sugar Nucleotides into Rat Liver Golgi. A New Golgi Marker Activity", <i>J. Cell Biol.</i> , 257(18):811-817 (1982).
CQ2	Stagljar et al., "New Phenotype of Mutations Deficient in Glucosylation of the Lipid-Linked Oligosaccharide: Cloning of the ALG8 Locus", <i>Proc. Natl. Acad. Sci. USA</i> , Vol. 91, pp. 5977-5981, June 1994.
CR2	Suzuki C., "Immunochemical and Mutational Analyses of P-Type ATPase Spf1p Involved in the Yeast Secretory Pathway", <i>Bioscience Biotechnology Biochemistry</i> 2001, Volume 65, Number 11, 2405-2411.
CS2	Takahashi N. et al., "Comparative Structural Study of the N-Linked Oligosaccharides of Human Normal and Pathological Immunoglobulin", <i>Biochemistry</i> , 1987, Volume 26, pages 1137-1144.
CT2	Takeuchi, "Trial for Molecular Breeding of Yeast for the Production of Glycoprotein Therapeutics", <i>Trends in Glycoscience and Glycotechnology</i> , 9:S29-S35 (1997).
CU2	Tremblay et al., "Cloning and Expression of a Specific Human α 1,2-Mannosidase that Trims Man9GlcNAc2 to Man8GlcNAc2 Isomer B during N-Glycan Biosynthesis", <i>Glycobiology</i> , 1999, Volume 9, Number 10, pages 1073-1078.
CV2	Umana et al., "Tetracycline-Regulated Overexpression of Glycosyltransferase in Chinese Hamster Ovary Cells", <i>Biotechnol. Bioeng.</i> , 65(5):542-9 (1999)
CW2	Umana et al., "Engineered glycoforms of an antineuroblastoma IgG1 with optimized antibody-dependent cellular cytotoxic activity", <i>Nat. Biotechnol.</i> , 17(2):176-80 (1999)
CX2	Vasquez-Reyna, et al., "Biosynthesis of Glycoproteins in Candida Albicans: Biochemical Characterization of a Soluble Alpha-Mannosidase", <i>FEMS Microbiology Letters</i> , 1993, Volume 106, pages 321-326.
CY2	Verostek et al., "Glycoprotein Biosynthesis in the alg3 Saccharomyces Cerevisiae mutant. II. Structure of Novel Man6-10GlcNAc2 Processing Intermediates on Secreted Invertase", <i>J. Biol. Chem.</i> , June 5, 1993 (268) 16:12095-12103.
CZ2	Weikert, et al., "Engineering Chinese Hamster Ovary Cells to Maximize Sialic Acid Content of Recombinant Glycoproteins", <i>Nature Biotechnology</i> , 17(11): 1116-1121 (1999).
CA3	Yip et al., "Cloning and analysis of the <i>Saccharomyces cerevisiae</i> MNN9 and MNN1 genes required for complex glycosylation of secreted proteins", <i>Proc. Natl. Acad. Sci. USA</i> , 91(7):2723-7 (1994).
CB3	Yoko-o et al., "Schizosaccharomyces Pombe Och1(+) Encodes Alpha-1,6-Mannosyltransferase that is involved in Outer Chain Elongation of N-Linked Oligosaccharides", <i>FEBS Lett.</i> , 489(1):75-80 (2001).
CC3	Yoshida, et al., "1-2-alpha-D- mannosidase from <i>Penicillium citrinum</i> : molecular and enzymic properties of two isoenzymes", <i>Biochem. J.</i> 290 (Pt2):349-354 (1993).
CD3	Yoshida et al. STT3, a Novel Essential Gene Related to the PKC1/STT1 Protein Kinase Pathway, is Involved in Protein Glycosylation in Yeast", <i>Gene</i> 1995 October 16;164(1):167-72.

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	CE3	Yoshida, et al., "Expression and characterization of rat EDP-N-acetylglucosamine: α -3-D-mannoside β -1,2-N-acetylglucosaminyltransferase I in <i>Saccharomyces cerevisiae</i> ", <i>Glycobiology</i> , 9 (1):53-8 (1999).	
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*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

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